

Citation:

Schulze MB, Manson JE, Willett WC, Hu FB. Processed meat intake and incidence of Type 2 diabetes in younger and middle-aged women. *Diabetologia*. 2003;46(11):1465-1473.

PubMed ID: [14576980](#)

Study Design:

Prospective cohort study

Class:

B - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate the association between processed and other meat intake and incidence of type 2 diabetes in a large cohort of young and middle-aged women

Inclusion Criteria:

- Female U.S. nurses aged 24 to 44 years of age at study initiation in 1989
- Completed a self-administered dietary questionnaire to imply informed consent

Exclusion Criteria:

- Left more than nine items blank on a dietary questionnaire
- Consumed total energy intake less than 500 kcal/day or more than 3,500 kcal/day
- Reported history of diabetes, cancer (except non-melanoma skin cancer) or cardiovascular disease on either the 1989 or 1991 questionnaire
- Had no physical activity data in 1991

Description of Study Protocol:**Recruitment**

- Subjects were recruited from the Nurses' Health Study II of 116,671 female U.S. nurses in 1989.
- This cohort was followed using biennial mailed questionnaires with a follow-up rate exceeding

90% for every 2-year period

Design

- 8-year follow-up prospective cohort study

Statistical Analysis

- Relative risk (RR) was estimated using Cox proportional hazards analysis stratified on 5-year age categories.
- The 1991 intake was used for the follow-up between 1991 and 1995, and the average of the 1991 and 1995 intakes for the follow-up between 1995 and 1999 to reduce within-subject variation and best represent long-term diet.
- Confirmatory factor analysis was used to test an acceptable model of the data.
- The Goodness-of-fit was determined by the Goodness-of-Fit Index, the Non-normed-Fit Index, the Comparative Fit Index, the Root Mean Square Error of Approximation and the significance-of-factor loadings.
- Patterns scores were calculated for each individual by summing the standardized food intakes for each pattern.
- A P value of less than 0.05 was considered statistically significant.

Data Collection Summary:

Timing of Measurements

- Food consumption was assessed using a 133-food item semi-quantitative food frequency questionnaire (FFQ). The correlation coefficients between FFQ and multiple dietary records were established: 0.56 for hot dogs, 0.70 for bacon, 0.55 for other processed meats, 0.38 for hamburgers, 0.46 for red meat as a main dish or mixed dish, 0.58 for poultry, and 0.66 for fish.
- Age, weight, smoking status, contraceptive use, post-menopausal hormone replacement therapy, history of high blood pressure and high blood cholesterol was collected by biennial questionnaires.
- Women reporting a new diagnosis of diabetes on any of the biennial questionnaires were sent supplementary questionnaires asking about diagnosis, treatment and history of ketoacidosis to distinguish between type 1 and type 2 diabetes. Self-reported diabetes cases were confirmed in accordance with the criteria of the National Diabetes Data Group. Diabetes self-reports in this cohort was validated.
- In 1991 and 1997, physical activity was computed as metabolic equivalents per week using the duration per week of various forms of exercise, weighting each activity by its intensity level.

Dependent Variables

- Incident cases of type 2 diabetes

Independent Variables

- Processed meat intake

Control Variables

- BMI, physical activity, alcohol intake and smoking status
- Fatty acids, cholesterol, magnesium, fiber and caffeine
- Western dietary pattern

Description of Actual Data Sample:

Initial N: 116,671 women at study initiation

Attrition (final N): 91,246 for the analyses indicating 22% dropout rate

Age: Participants were aged 26 to 46 years of age at baseline in 1991

Ethnicity: not described

Other relevant demographics: not described

Anthropometrics: Whether groups were same or different on BMI is not described.

Location: Brigham and Women's Hospital in Boston, Massachusetts

Summary of Results:

Key findings

- 741 incident cases of confirmed type 2 diabetes were identified during 716,276 person-years of follow-up.
- The relative risk adjusted for potential non-dietary confounders was 1.91 (95% CI: 1.42-2.57) in women consuming processed meat five times or more a week compared with those consuming processed meat less than once a week ($P<0.001$ for trend).
- Further adjustment for intakes of magnesium, cereal fiber, glycemic index, and caffeine or for a Western dietary pattern did not appreciably change the results and associations remained strong after adjustment for fatty acid and cholesterol intake.
- Frequent consumption of bacon, hot dogs, and sausage was each associated with an increased risk of diabetes.
- While total red meat (beef or lamb as main dish, pork as main dish, hamburger, beef, pork or lamb as sandwich or mixed dish) intake was associated with an increased risk of diabetes, this association was attenuated after adjustment for magnesium, cereal fiber, glycemic index, and caffeine (RR: 1.44; 95% CI: 0.92-2.24).

Author Conclusion:

- Results from this study suggest that diets high in processed meats could increase the risk for developing type 2 diabetes.

Reviewer Comments:

First, this is a prospective cohort observational study. The focus is on comparison of existing convenience groups getting different exposures. Thus, having a large sample size is more relevant than getting a representative sample. Second, objective biochemical measures from blood samples could be collected to verify unmeasured dietary exposures. The observed associations might be less biased. Authors also noted that adjusting red and processed meat for Western pattern in the analysis did not control other important components of the Western pattern such as refined grain and sweets, while measuring its effect on type 2 diabetes.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	Was the research question clearly stated?	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes

2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	Were study groups comparable?	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%).	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blinding used to prevent introduction of bias?	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	No

5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening/factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	N/A
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes

8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	N/A
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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